New Prescription and OTC Medication Update

Joanne Fazio-Gosser
faziogos@uiwtx.edu

Bradi L. Frei
frei@uiwtx.edu

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Financial Disclosures

- Bradi L. Frei and Joanne Fazio-Gosser have no relevant financial disclosures.
Pharmacist Objectives

- Identify the new prescription and OTC medications approved by the FDA that are most clinically relevant to general practice in 2020
- Explain relevant indications, efficacy, pharmacokinetics, safety, and dosing of new medications
- Evaluate and summarize how the new medications differ from existing medications on the market
Technician Objectives

- Identify the new prescription and OTC medications approved by the FDA that are most clinically relevant to general practice in 2020
- Discuss relevant indications, efficacy, pharmacokinetics, safety, and dosing of new medications
- List the drug class the new medications belong to and similar existing medications on the market
Ozanimod (Zeposia®)

- FDA Indication: relapsing forms of multiple sclerosis (MS)

- Dose: Administered orally once daily

- Test patient for antibodies for varicella zoster virus prior to starting

- MOA: sphingosine 1 phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5

<table>
<thead>
<tr>
<th>Days</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1-4</td>
<td>0.23 mg once daily</td>
</tr>
<tr>
<td>Days 5-7</td>
<td>0.46 mg once daily</td>
</tr>
<tr>
<td>Day 8 and thereafter</td>
<td>0.92 mg once daily</td>
</tr>
</tbody>
</table>

FDA – Food and Drug Administration; MOA – mechanism of action
Zeposia (ozanimod) Package Insert.
Ozanimod (Zeposia®)

- **Contraindications** – Recent CV events, severe untreated sleep apnea, MOA inhibitors, presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sinoatrial block

- **Warning** – Infections, bradyarrhythmia and AV conduction delays, liver injury, fetal risk, increased BP, decline in pulmonary function, macular edema

- **Drug Interactions**
  - Avoid Strong CYP2C8 inducers and inhibitors
  - BCRP Inhibitors
  - Avoid live vaccines

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory infection</td>
<td>26%</td>
</tr>
<tr>
<td>Hepatic transaminase elevation</td>
<td>10%</td>
</tr>
<tr>
<td>Orthostatic hypotension</td>
<td>4%</td>
</tr>
<tr>
<td>UTI</td>
<td>4%</td>
</tr>
<tr>
<td>Back pain</td>
<td>4%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>4%</td>
</tr>
</tbody>
</table>
Opicapone (Ongentys®)

- FDA Indication: Adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes

- Dose: 50 mg po daily at bedtime without food

- MOA: catechol-O-methyltransferase (COMT) inhibitor
Opicapone (Ongentys®)

- Contraindications – non-selective MAO inhibitors, history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms
- Warning – CV with other drugs metabolized with COMT, falling asleep, hypotension, syncope, dyskinesia, impulse control, withdrawal
- Drug Interactions
  - Drugs metabolized by COMT
  - MAO inhibitors

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyskinesia</td>
<td>20%</td>
</tr>
<tr>
<td>Constipation</td>
<td>6%</td>
</tr>
<tr>
<td>Blood creatine kinase increased</td>
<td>5%</td>
</tr>
<tr>
<td>Hypotension/syncope</td>
<td>5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>4%</td>
</tr>
</tbody>
</table>
Remimazolam besylate (Byfavo®)

° FDA Indication: induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less

° Dose: Initial 5 mg IV push, may supplement 2.5 mg IV at least 2 minutes after initial dose

° MOA: binds to brain benzodiazepine sites
Remimazolam besylate (Byfavo®)

- Contraindications – hypersensitivity to dextran
- Warning – trained personnel with proper equipment, hypersensitivity reactions, neonatal sedation, theoretical risk of pediatric neurotoxicity
- Drug Interactions
  - CNS depressant medications

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>39%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>20%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>11%</td>
</tr>
<tr>
<td>Diastolic hypertension</td>
<td>10%</td>
</tr>
<tr>
<td>Hypoxia</td>
<td>22%</td>
</tr>
<tr>
<td>Diastolic hypotension</td>
<td>8%</td>
</tr>
</tbody>
</table>
Fostemsavir tromethamine (Rukobia®)

- FDA Indication: HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection

- Dose: 600 mg po BID

- MOA: HIV-1 antiretroviral agent
Fostemsavir tromethamine (Rukobia®)

- **Contraindications** – hypersensitivity to fostemsavir, coadministered strong cytochrome P450 3A inducers

- **Warning** – Immune reconstitution syndrome, QTc prolongation, Increase hepatic enzymes with Hepatitis B or C co-infection

- **Drug Interactions**
  - CYP 3A Inducers
  - Birth control
  - Statins
  - Meds that prolong QTc

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>10%</td>
</tr>
<tr>
<td>Increased creatinine</td>
<td>19%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4%</td>
</tr>
<tr>
<td>Headache</td>
<td>4%</td>
</tr>
<tr>
<td>Immune Reconstitution Inflammatory Syndrome</td>
<td>2%</td>
</tr>
</tbody>
</table>

Rukobia (fostemsavir tromethamine) Package insert
Risdiplam (Evrysdi®)

- FDA Indication: Spinal muscular atrophy
- Dose: Administered orally once daily after meal

<table>
<thead>
<tr>
<th>Age and Body Weight</th>
<th>Recommended Daily Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months to less than 2 years of age</td>
<td>0.2 mg/kg</td>
</tr>
<tr>
<td>2 years of age and older weighing less than 20 kg</td>
<td>0.25 mg/kg</td>
</tr>
<tr>
<td>2 years of age and older weighing 20 kg or more</td>
<td>5 mg</td>
</tr>
</tbody>
</table>

- MOA: survival of motor neuron 2 (SMN2) splicing modifier which distributes and increases SMN protein

FDA – Food and Drug Administration; MOA – mechanism of action
Evrysdi (risdiplam) Package Insert
Risdipram (Evryrsdi®)

- Contraindications – none

- Warning – none

- Drug Interactions
  - Avoid coadministration with drugs that are substrates of multidrug and toxin extrusion (MATE) transporters

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>22%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>17%</td>
</tr>
<tr>
<td>Rash</td>
<td>17%</td>
</tr>
</tbody>
</table>
Clascoterone (Winlevi®)

- FDA Indication: topical treatment of acne vulgaris
- Dose: 1% cream applied topically twice per day
- MOA: androgen receptor inhibitor

FDA – Food and Drug Administration; MOA – mechanism of action
Winlevi (clascoterone) Package Insert
Clascoterone (Winlevi®)

- Contraindications: none
- Warnings: local skin reactions, HPA axis suppression
- Drug Interactions: None

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scaling/dryness</td>
<td>10.5%</td>
</tr>
<tr>
<td>Erythema/redness</td>
<td>12.2%</td>
</tr>
<tr>
<td>Itching</td>
<td>7.7%</td>
</tr>
</tbody>
</table>
Remdesivir (Veklury®)

- FDA Indication: coronavirus disease 2019 (COVID-19) requiring hospitalization adults and pediatric patients (12 years and older and weighing at least 40 kg)

- Dose: Adults and pediatric patients ≥12 years old and weighing ≥40 kg: 200 mg IV on Day 1, then daily 100 mg IV starting on Day 2

- Only administered in hospital setting or similar facility

- MOA: SARS-CoV-2 nucleotide analog RNA polymerase inhibitor

- Available in 2 formulations – solution can only be used in adults and children 12 years of age and older and weighing at least 40 kg

Veklury (remdesivir) Package Insert. FDA – Food and Drug Administration; MOA – mechanism of action
Remdesivir (Veklury®)

- Contraindications: none

- Warnings: hypersensitivity, increase in transaminases

- Drug Interactions: No clinical data but cell culture experiments suggest possible antagonism with chloroquine phosphate or hydroxychloroquine sulfate and is not recommended

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>3-5%</td>
</tr>
<tr>
<td>AST increased</td>
<td>3-6%</td>
</tr>
<tr>
<td>ALT increased</td>
<td>2-7%</td>
</tr>
</tbody>
</table>
20 new approvals in Hem/Onc in 2020

Avapritinib
Tazemetostat
Isatuximab
Tucatinib
Pemigatinib
Sacituzumab govitecan-hziy
Capmatinib
Selpercatinib
Ripretinib
Fluoroestradiol F18
Lurbinectedin
Decitabine and cedazuridine
Tafasitamab-cxix

Belantamab mafodotin-blmf
Copper Cu 64 dotatate
Pralsetinib
Naxitamab-gqgk
Gallium 68 PSMA-11
Margetuximab
Relugolix
Tucatinib (Tukysa®)

- FDA Indication: Advanced unresectable or metastatic HER 2 positive breast cancer in combination with capecitabine

- Dose: 300 mg (two 150 mg tablets) orally twice daily with or without food
- For severe hepatic impairment, 200 mg orally twice daily

- MOA: tyrosine kinase inhibitor of HER2
Tucatinib (Tukysa®)

- Contraindications – None
- Warning – diarrhea, hepatotoxicity
- Drug Interactions
  - Avoid Strong Inducers of CYP3A
  - Avoid Strong and Moderate CYP2C8 Inducers
  - Avoid Strong Inhibitors CYP2C8
  - Avoid Strong CYP3A Substrates
  - Reduce dose of P-gp substrates

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>81% (12.5%)</td>
</tr>
<tr>
<td>Palmar-Plantar erythrodysesthesia</td>
<td>63% (13%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>58% (3.7%)</td>
</tr>
<tr>
<td>Hepatotoxicity</td>
<td>42% (9.2%)</td>
</tr>
<tr>
<td>Stomatitis</td>
<td>32% (2.5%)</td>
</tr>
</tbody>
</table>
Pemigatinib (Pemazyre®)

- FDA Indication: 1st line unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or other rearrangement
- Dose: 13.5 mg orally once daily for 14 days followed by 7 days off therapy with or without food
- For severe hepatic or renal impairment, pemigatinib is not recommended
- MOA: kinase inhibitor targets FGFR 1,2, and 3
Pemigatinib (Pemazyre®)

- Contraindications – None

- Warning – retinal pigment epithelial detachment, hyperphosphatemia

- Drug Interactions
  - Avoid Strong and Moderate CYP3A Inhibitors and Inducers

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>47% (2.7%)</td>
</tr>
<tr>
<td>Hyperphosphatemia</td>
<td>60% (0)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>49% (0)</td>
</tr>
<tr>
<td>Nail toxicity</td>
<td>43% (2.1)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>42% (4.8%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>40% (2.1)</td>
</tr>
<tr>
<td>Dysgeusia</td>
<td>40% (0)</td>
</tr>
</tbody>
</table>
Capmatinib (Tabrecta™)

- FDA Indication: metastatic non-small cell lung cancer with mutation causing mesenchymal-epithelial transition (MET) exon 14 skipping
- Dose: 400 mg po BID
- MOA: kinase inhibitor targets MET reduces cancer cell growth

FDA – Food and Drug Administration; MOA – mechanism of action
Tabrecta (capmatinib) Package Insert
Capmatinib (Tabrecta™)

○ Contraindications – None

○ Warning – interstitial lung disease, hepatotoxicity, photosensitivity

○ Drug Interactions
  • Avoid Strong and Moderate CYP3A inducers

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral edema</td>
<td>52%</td>
</tr>
<tr>
<td>Nausea</td>
<td>44%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>32%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>28%</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>24%</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>21%</td>
</tr>
<tr>
<td>Increased creatinine</td>
<td>62%</td>
</tr>
</tbody>
</table>
Rx to OTC Switch

- Sklice (ivermectin) lotion
- Pataday Products
- Voltaren Arthritis Pain (diclofenac sodium)
Lactitol (Pizensy®)

- FDA Indication: Lactitol is indicated for chronic idiopathic constipation (CIC) in adults.

- Dose and Administration: 20gm orally once daily preferably with meals.
  - Reduce the dosage to 10gm once daily for persistent loose stools.
  - Multidose bottle preparation: 2 caps dissolved in 4-8 ounces of water, juice or other common beverage.

- MOA: Lactitol exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect in the colon.
Lactitol (Pizensy®)

° Contraindications: Lactitol is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

° Warning: None

° Drug Interactions: Lactitol may reduce the absorption of concomitantly administered oral medications. Administer oral medications at least 2 hours before or 2 hours after PIZENSY.
Lactitol (Pizensy®) Adverse Reactions

Study provides the incidence of adverse reactions in Study 1 reported in at least 3% of patients in the PIZENSY treatment group and at higher incidence than placebo.

<table>
<thead>
<tr>
<th>Condition</th>
<th>PIZENSY (\pm) N=291 (%)</th>
<th>Placebo N=302 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Respiratory Tract Infection (\dagger)</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Flatulence</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Increased blood creatinine phosphokinase (\dagger)</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Abdominal Distention</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Increased blood pressure (\dagger)</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

\(\dagger\) reported in at least 3% of patients and greater than placebo
\(\dagger\) 74 of 291 patients in the PIZENSY group at least temporarily reduced their dose
\(\dagger\) Upper respiratory tract infection includes the terms viral upper respiratory tract infection and nasopharyngitis.
\(\dagger\) Increased blood creatinine phosphokinase includes the term blood creatinine phosphokinase myocardial band (MB) increased.
\(\dagger\) Increased blood pressure includes the term Hypertension.
Vibegron (Gemtesa®)

- **FDA Indication:** Vibegron is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency in adults.

- **Dose and Administration:** Recommended dose is 75mg once daily.
  - Swallow tablet whole with water or tablet may be crushed and mixed with applesauce.

- **MOA:** Vibegron is a selective human beta-3 receptor agonist. Activation of the Beta-3 adrenergic receptor increases bladder capacity by relaxing the detrusor smooth muscle during bladder filling.
Vibegron (Gemtesa®)

- **Contraindications:** Vibegron is contraindicated in patients with known hypersensitivity to vibegron or any components of the product.

- **Warnings:** Urinary retention has been reported in patients taking Vibegron. Discontinue Vibegron in patients who develop urinary retention.

- **Drug Interactions:** Concomitant use of Vibegron increases digoxin maximal concentrations. Serum digoxin concentrations should be monitored before initiating and during therapy and should be used for titration of digoxin dose.
### Vibegron (Gemtesa®) Adverse Reactions

Adverse Reactions, Exceeding Placebo Rate, Reported in ≥2% of Patients Treated with GEMTESA 75 mg for up to 12 Weeks in Study 3003

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>GEMTESA 75 mg n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>545</td>
<td>540</td>
</tr>
<tr>
<td>Headache</td>
<td>22 (4.0)</td>
<td>13 (2.4)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>15 (2.8)</td>
<td>9 (1.7)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12 (2.2)</td>
<td>6 (1.1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>12 (2.2)</td>
<td>6 (1.1)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>11 (2.0)</td>
<td>4 (0.7)</td>
</tr>
</tbody>
</table>
Oliceridine (Olinvyk®)

- **FDA Indication:** Oliceridine is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

- **Dose and Administration:** For intravenous administration only.
  - Individual single doses greater than 3mg have not been evaluated.
  - The cumulative daily dose should not exceed 27mg.
  - Draw directly into a PCA syringe or IV bag without diluting. Titration is necessary to prevent respiratory and CNS depression.

- **MOA:** Oliceridine is a full opioid agonist and is relatively selective for the mu-opioid receptor. Therapeutic action is analgesia. No ceiling effect for this drug.
Oliceridine (Olinvyk®)

- **Contraindications:** Patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting, known or suspected gastrointestinal obstruction, anaphylaxis to Oliceridine.

- **Warnings:** Black box warning: addiction, abuse, and misuse; life-threatening respiratory depression; neonatal opioid withdrawal syndrome: risks from concomitant use with benzodiazepines or other CNS depressants.

- **Drug Interactions:**
  - CYP2D6 inhibitors and increase plasma concentrations of Oliceridine (paroxetine, fluoxetine and bupropion).
  - CYP3A4 inhibitors can increase plasma concentrations (macrolide antibiotics such as erythromycin,azole-antifungals such as ketoconazole and protease inhibitors such as ritonavir).
  - Serotonergic drugs will cause serotonin syndrome (SSRI and SNRI) MONITOR.
  - Mixed agonist/antagonist and partial opioid analgesics may reduce analgesic effect and precipitate withdrawal.
Oliceridine (Olinvyk®)

° Cont..
  • Muscle relaxants => respiratory depression
  • Diuretics in combo =< efficacy of diuretics. MONITOR BP
  • Anticholinergic drugs => urinary retention and constipation

° Adverse Reactions:
  • Addiction, abuse and misuse
  • Respiratory depression
  • Neonatal opioid withdrawal
  • Adrenal insufficiency
  • Severe hypotension
  • GI Effects(>10%)
  • Seizures
  • Withdrawal
Bempedoic Acid (Nexletol®)

- **FDA Indication:** Bempedoic Acid is indicated as an adjunct to diet and maximally tolerated as a statin therapy for treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

- **Dose and Administration:** Recommended dosage of Bempedoic Acid, in combination with maximally tolerated statin therapy is 180mg administered once daily.
  - Can be taken with or without food.

- **MOA:** Bempedoic acid is an adenosine triphosphate-citrate lyase (ACL inhibitor) that lowers low-density lipoprotein cholesterol (LDL-C) by inhibition of cholesterol synthesis in the liver.
Bempedoic Acid (Nexletol®)

- Contraindications: None
- Warnings:
  - Hyperuricemia: Bempedoic Acid inhibits renal tubular OAT2 and may increase blood uric acid levels which may lead to development of gout.
  - Tendon Rupture: Bempedoic Acid is associated with increased risk of tendon rupture or injury. This happens more often in patients over 60, patients with renal failure, and those taking fluoroquinolone drugs.

- Drug Interactions:
  - Avoid concomitant use of Bempedoic Acid with simvastatin > than 20mg
  - Avoid concomitant use of Bempedoic Acid pravastatin > 40mg (both may increase risk of myopathy)
Bempedoic Acid (Nexletol®) Adverse Reactions

Study 1 and 2 Adverse Reactions > 2% and Greater than placebo) in NEXLETOL-Treated Patients with ASCVD and HeFH

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>NEXLETOL + Statin and ± Other Lipid Lowering Therapies (N = 2009) %</th>
<th>Placebo (N = 999) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>3.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>3.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Back pain</td>
<td>3.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Abdominal pain or discomfort†</td>
<td>3.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>3.0</td>
<td>1.7</td>
</tr>
</tbody>
</table>
Abametapir Lotion (Xeglyze®)

- **FDA Indication:** Abametapir lotion is indicated for the topical treatment of head lice infestation in patients 6 months of age and older. Abametapir lotion should be used in overall lice management program.

- **Dose and Administration:**
  - For topical use only.
  - Shake well before use. Apply to dry hair in an amount (up to the full content of one bottle) sufficient to thoroughly coat the hair and scalp. Massage into scalp and throughout hair. Avoid contact with eyes. Leave on hair and scalp for 10 minutes then rinse with warm water. Use fine-tooth comb to remove dead lice and nits. Hair can be shampooed at any time.

- **MOA:** Abametapir lotion is a metalloproteinase inhibitor. Metalloproteinases have a role in physiological process critical to egg development and survival of lice.
Abametapir lotion (Xeglyze®)

- Contraindications: None
- Warnings:
  - Risk of Neonatal Benzyl Alcohol Toxicity resulting in “gaspig syndrome” and low birth weight.
  - Risk of Benzyl Alcohol Toxicity from Accidental Ingestion. Contact Poison Control Center 1-800-222-1222.

- Drug Interactions:
  - Studies suggest there is a potential for inhibition of cytochrome P450, 3A4, 2B6 and 1A2 enzymes following a single application. Use of Abametapir lotion with drugs that are substrates of these enzymes may lead to increased concentrations of these drugs.
### Abametapir Lotion (Xeglyze®) Adverse Reactions

#### Table 1: Adverse Reactions Occurring in ≥ 1% of the XEGLYZE Group and at a Greater Frequency than in the Vehicle Group (Trials 1 and 2)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>XEGLYZE N=349 Subjects (%)</th>
<th>Vehicle N=350 Subjects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>14 (4.0)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Rash</td>
<td>11 (3.2)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Skin burning sensation</td>
<td>9 (2.6)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Contact dermatitis</td>
<td>6 (1.7)</td>
<td>4 (1.1)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6 (1.7)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>4 (1.2)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Hair color changes</td>
<td>3 (1)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
Tirbanibulin (Klisyri®)

- **FDA Indication:** Tirbanibulin is indicated for topical treatment of actinic keratosis on the face of scalp.

- **Dose and Administration:** Apply sufficient amount to evenly cover up to 25cm² treatment field on the face or scalp once daily for 5 consecutive days using one single dose packet per application.

- **MOA:** Tirbanibulin is a microtubule inhibitor for topical use. The MOA for actinic keratosis is unknown.
Tirbanibulin (Klisyri®)

- Contraindications: None
- Warnings:
  - Eye irritation. Avoid contact of drug into the eye during application. Wash hands after application. Flush eyes if accidental exposure.
  - Local Skin reactions including severe reactions (erythema, flaking/scaling, crusting, swelling, pustulation and ulceration)
- Drug Interactions: None
Tirbanibulin (Klisyri®) Adverse Reactions

Clinical Trial showed that most reactions were in the moderate category which is distinct presence on face and scalp.

<table>
<thead>
<tr>
<th>Local Skin Reactions</th>
<th>Mild n (%)</th>
<th>Moderate n (%)</th>
<th>Severe n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>76 (22%)</td>
<td>223 (63%)</td>
<td>22 (6%)</td>
</tr>
<tr>
<td>Flaking/ Scaling</td>
<td>92 (26%)</td>
<td>166 (47%)</td>
<td>31 (9%)</td>
</tr>
<tr>
<td>Crusting</td>
<td>107 (30%)</td>
<td>50 (14%)</td>
<td>7 (2%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>102 (29%)</td>
<td>32 (9%)</td>
<td>2 (&lt;1%)</td>
</tr>
<tr>
<td>Vesiculation/ Pustulation</td>
<td>25 (7%)</td>
<td>2 (&lt;1%)</td>
<td>2 (&lt;1%)</td>
</tr>
<tr>
<td>Erosion/ Ulceration</td>
<td>32 (9%)</td>
<td>9 (3%)</td>
<td>0</td>
</tr>
</tbody>
</table>
Setmelanotide (Imcivree®)

- **FDA Indication:** Setmelanotide is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to specific protein deficiencies confirmed by genetic testing.

- **Dose and Administration:**
  - Adults and Pediatric Patients over 12: Starting dose is 2mg injected subq once daily for 2 weeks. Monitor for GI side effects. If not tolerated reduce to 1mg daily until tolerated, then increase to 2mg. If 2mg dose is tolerated increase dose to 3mg after the initial 2 weeks.
  - Pediatric patients 6-12 years: Starting dose is 1mg daily for 2 weeks. If tolerated increase to 2mg daily. If not tolerated, decrease to 0.5mg until tolerated and then increase back up to 1mg.

- **MOA:** Setmelanotide is a MC4 receptor agonist. MC4 receptors in the brain are involved in regulation of hunger, satiety, and energy expenditure. Patients with obesity due to POMC, PCSK1 and LEPR deficiency have insufficient activation of the MC4 receptor. Setmelanotide may re-establish MC4 receptor pathway activity to reduce hunger and promote weight loss.
Setmelanotide (Imcivree®)

- Contraindications: None
- Warnings:
  - Depression and suicidal ideation.
  - Skin pigmentation and darkening of pre-existing nevi.
  - Risk of serious adverse reactions due to benzyl alcohol preservative in neonates and low birth weight infants.
  - Disturbance in sexual arousal: spontaneous penile erections in males and sexual adverse reactions in females.
- Drug Interactions: None
Setmelanotide (Imcivree®)

- Adverse Reactions: The most common (incidence >23%) were injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection and spontaneous penile erection.
Amisulpride (Barhemsys®)

- FDA Indication:
  - Amisulpride is indicated in adults for prevention of postoperative nausea (PONV) and vomiting either alone or in combination with an antiemetic of a different class.
  - Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

- Dose and Administration:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Adult Dosage Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of PONV</td>
<td>5 mg as a single intravenous injection infused over 1 to 2 minutes at the time of induction of anesthesia [see DOSAGE AND ADMINISTRATION (2.2)].</td>
</tr>
<tr>
<td>Treatment of PONV</td>
<td>10 mg as a single intravenous injection infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure [see DOSAGE AND ADMINISTRATION (2.2)].</td>
</tr>
</tbody>
</table>
MOA: Amisulpride is a selective dopamine-2 and dopamine-3 receptor antagonist. D2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Activation of CTZ relays stimuli to the vomiting center which is involved in emesis.

Contraindications: In patients with hypersensitivity to amisulpride.

Warnings:
- QT Prolongation: Avoid in patients with congenital long QT syndrome and in patients taking droperidol.

Drug Interactions:
- Dopamine Agonists: reciprocal antagonism of effects occurs between dopamine agonists (e.g. levodopa)
- Drugs prolonging QT Interval will cause additive effects (e.g. ondansetron)
Clinical trials indicate that doses of 5mg cause the following adverse reactions at >2%.

<table>
<thead>
<tr>
<th></th>
<th>BARHEMSYS 5 mg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=748</td>
<td>N=741</td>
</tr>
<tr>
<td>Chills</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Procedural hypotension</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>
Rimegepant ODT (Nurtec ODT®)

- FDA Indication: Rimegepant ODT is indicated for the acute treatment of migraine with or without aura in adults.

- Dose and Administration:
  - The recommended dose is 75mg taken orally as needed.
  - The maximum dose in a 24-hour period is 75mg
  - The safety of treating more than 15 migraines in 30 days has not been established.

- MOA: Rimegepant ODT is a calcitonin gene-related peptide receptor antagonist.
Rimegepant ODT (Nurtec ODT®)

- **Contraindications:** Rimegepant ODT is contraindicated in patients with a history of hypersensitivity. Delayed serious hypersensitivity reactions have occurred.

- **Warnings:** Hypersensitivity reactions, including dyspnea and rash, have occurred. Hypersensitivity can be delayed by several days after first administration. D/C drug if this occurs.

- **Drug Interactions:**
  - Concomitant administration with strong or moderate inducers of CYP3A can result in a significant reduction and loss of efficacy.
  - Concomitant administration with strong or moderate inhibitor of CYP3A4 can result in significant increase in exposure.
  - Concomitant administration with inhibitors of P-gp or BCRP can result in significant increase in exposure.

- **Adverse Reactions:** Same as contraindications and warnings.
Rimegepant ODT (Nurtec ODT®)

INSTRUCTIONS

1. Use dry hands when opening. Peel back the foil covering of one blister and gently remove Nurtec™ ODT. Do not push Nurtec™ ODT through the foil.

2. As soon as the blister is opened, remove Nurtec™ ODT and place on or under the tongue, where it will dissolve. No drink or water is needed.

3. Close blister pack and slide back into the carrier until it clicks. Do not store Nurtec™ ODT outside the blister pack for future use.
Eptinezumab (Vyepti®)

- **FDA Indication:** Eptinezumab is indicated for the preventive treatment of migraine in adults.

- **Dose and Administration:** Recommended dosage if 100mg administered by intravenous infusion every 3 months. Some patients may benefit from a dosage of 300mg.

- **MOA:** Eptinezumab is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.
Eptinezumab (Vyepti®)

- **Contraindications:** Eptinezumab is contraindicated in patients with serious hypersensitivity. Reactions have included angioedema.

- **Warnings:** Hypersensitivity reactions including angioedema, urticaria, facial flushing and rash have occurred in clinical trials. Most occurred during infusion and infusion had to be discontinued.

- **Drug Interactions:** None
Eptinezumab (Vyepti®) Adverse Reactions

Hypersensitivity reactions include multiple related adverse event terms such as hypersensitivity, pruritus, and flushing/hot flush that occurred on day of dosing.

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>VYEPTI 100 mg N=579</th>
<th>VYEPTI 300 mg N=574</th>
<th>Placebo N=588 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>6</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Hypersensitivity reactions*</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
Somapacitan-beco (SOGROYA®)

FDA Indication: Somapacitan-beco is a human growth hormone analog indicated for replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency.

Dose and Administration:
- Initial dose 1.5mg once weekly for naïve patients.
- Increase dose by 0.5mg to 1.5mg every 2 weeks until desired response is reached.
- Maximum dose is 8mg once weekly.
- Injected subcutaneously in abdomen or thigh once weekly.

MOA: Somapacitan-beco binds to dimeric GH receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects.
Somapacitan-beco (SOGROYA®)

° Contraindications: Acute critical illness, active malignancy, active proliferative or severe non-proliferative diabetic retinopathy.

° Warnings: Increased mortality in patients with acute critical illness, increased risk of neoplasms, glucose intolerance and diabetes mellitus, severe hypersensitivity, fluid retention, hypoadrenalism, hypothyroidism, pancreatitis.

° Drug Interactions:
  • Replacement Glucocorticoid Treatment: May need to increase dose of glucocorticoid for hypoadrenalism with initiation of Somapacitan-beco.
  • Cytochrome P450 metabolized drugs: Somapacitan-beco may alter clearance (Monitor).
  • Oral estrogen: Larger doses of Somapacitan-beco may be needed.
  • Insulin and Other Hypoglycemic Agents: Dose adjustment may be required.
Adverse Reactions: Reported in >2% of patients treated with Somapacitan-beco are back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsilitis, peripheral edema, vomiting, adrenal insufficiency, hypertension and blood creatinine phosphokinase increase, weight increase and anemia.
How do I keep up with these new medications?
Resources for Staying Up To Date

- FDA
  - Prescription-over-counter-otc-switch-list
  - Novel Drug Approvals for 2021
  - Subscribe to email alerts from FDA
- Interesting CE
- Talk with colleagues
- Part-time employment in a different area of pharmacy
Thank You

LinkedIn
www.linkedin.com/in/bradi-frei2001

Twitter
@BradiFrei

Email
frei@uiwtx.edu